

REMARKS/ARGUMENTS

Reconsideration of the application is requested.

Claims 1-15 remain in the application. Claims 1, 3, 5, 6, 12 and 14 have been amended.

More specifically with regard to the amendment and the required support in the specification:

- **Claim 1:** The needle guide with its conical entry segment and its cylindrical stabilization segment is described on page 12, lines 6-9.
- **Claims 1, 5:** The two functional positions and the locking of the system in the first functional position are described throughout. The tracks 10 and 11 are shown with different lengths and the different projection lengths of the needle are mentioned, for example, on page 13 of the specification.
- **Claim 3:** One of the tracks 10 and 11 leads to the first functional position and the other track leads to the second functional position. Support is found on page 13 of the specification.
- **Claims 6, 14:** The membrane and its sealing and closure functionality are described on page 12, lines 12-17, of the specification.

This leads us to the art rejection. The primary rejection is based on the Examiner's allegation that claims 1 and 4 are anticipated under 35 U.S.C. § 102(e) by Cherif Cheikh (US 6,896,670). In this regard, it is not entirely clear why claims 3, 8, 6, and 9 are discussed in the section dealing with the anticipation rejection on pages 2 and 3.

Cherif Cheikh does not have a needle guide with a conical segment and a cylindrical segment. Further, the reference assembly cannot be locked in a first functional position at which the needle projects a different amount from a second functional position. For these reasons alone, the amended claim 1 is not anticipated.

Claim 1 is also not rendered obvious by the primary reference or by any combination, because none of the references show these features or fairly suggest the same.

With regard to claim 5, Cherif Cheikh does not provide for a plurality of functional positions. Further, the reference does not have a receiver that is “mountable” to a distal end of a syringe with a hypodermic needle, as claimed.

The “seal” at the tip of the Cherif Cheikh assembly and in the slots 40 (Fig. 5). According to the patent, however, the seal “is preferably of easily friable material such as wax,” col. 2, lines 65-66. Once the needle has pushed through the seal, the same is broken or it falls out. As the needle is retracted into the cap 22, the seal does not close again. That is, the seal is not formed of a material that is able to close the opening after the needle is pulled back. As previously discussed, none of the other references provide a hint towards the forward seal. Claims 6 and 14 are patentable over the art of record.

With regard to claim 12 – and also with reference to the remaining claims – it should be noted that the reference Cherif Cheikh does not deal with a syringe device that has a luer lock and the corresponding attachment of the forward parts (i.e., the

needle with the luer lock and the protective cap that is mounted with its sleeve at the luer lock. Further, the claims define the protective cap to slide over the receiver, i.e., over the syringe barrel. The primary reference, therefore, is not even pertinent with regard to claim 12.

The most important distinction between the claimed invention and the disclosure of Cherif Cheikh resides in their respective concepts: The reference provides for a complete system, where a protective cap slides inside and into the barrel and a rod pushes a solid medicament carrier out of the needle. The invention, on the other hand, provides for a needle cap assembly which attaches to a conventional syringe with a barrel, a plunger (which pressurizes the inside of the barrel to express a liquid), and a forward luer lock. The needle cap assembly is a separate unit that is provided for attachment (e.g., "mountable") to the luer lock end of the syringe. The needle cap then slides over the barrel, not inside the barrel.

The additional references were discussed in detail in our earlier responses. Our argumentation in the Brief on Appeal is specifically incorporated by reference, as are our remarks in the response dated October 2, 2006. None of the prior art references, whether taken alone or in combination, anticipate the claimed invention nor do they render the claims obvious.

The rejection of claims 2, 3, and 5-9 over the combined teachings of Cherif Cheikh and Grabis et al. (US 6,322,540) under 35 U.S.C. § 103 is believed to be moot in light of the amendment to the claims. Specifically, the secondary reference Grabis et al. cannot make up for the shortcomings of the primary reference, as discussed

above. Neither Grabis et al. nor Cherif Cheikh provide for an assembly that provides for two or more functional positions and which can be locked in a first functional position. With regard to claim 1, the secondary reference does not have a needle guide. With regard to claim 5, the secondary reference does not provide a fair suggestion to modify the Cherif Cheikh assembly to provide for two or more functional positions.

The rejection of claims 10, 12, 14, and 15 over the combined teachings of Cherif Cheikh and Grabis et al., and further in view of Lee et al. (US 5,201,721) under 35 U.S.C. § 103 is also believed to be moot in light of the amendment to the claims. The disclosure of Lee et al. is quite similar to that of Grabis et al. and, as such, the further reference cannot properly modify the primary combination to provide for an assembly with two or more functional positions. In addition, the seal of claim 14 is not rendered obvious by the friable wax plug provided by Cherif Cheikh.

The rejection of claim 11 is based on “lee in view of Cherif Cheikh in view of Grabis as applied to claim 3” and in view of Gregorio (US 5,346,475) under 35 U.S.C. § 103. We are not certain that “Lee” should have been mentioned in this context, because Lee et al. had not been applied to claim 3. Either way, however, the combined teachings – with or without Lee et al. – cannot render obvious the claimed invention.

Gregorio is concerned with protecting against “serious harm from a puncture from a used needle.” Col. 1, line 55. The needle cap of the reference, once the needle is covered “cannot reverse its travel.” Abstract. That is, Gregorio starts out with a fully

exposed needle (cf. Fig. 1). Only after the syringe is used is the needle pulled back into its "hiding position" and it cannot be moved back out into a functional position.

Gregorio, therefore, cannot render obvious an assembly that provides "for movement from the closed position to, and locking in, a first position," as recited in claim 1 (and its dependent claim 11). The combination presented by the Examiner does not render claim 11 unpatentable.

In view of the foregoing, the allowance of the claims is solicited.

Petition for extension is herewith made. The extension fee for response subsequent to the shortened statutory period of pursuant to Section 1.136(a) and in accordance with Section 1.17 is enclosed herewith. Please charge any other fees which might be due with respect to Sections 1.16 and 1.17 to the Deposit Account of Lerner Greenberg Stermer LLP, No. 12-1099.

Respectfully submitted,

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